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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/084,691 05/26/98 BUKH

J 2026-4116US2

EXAMINER

HM31/0828

NATIONAL INSTITUTES OF HEALTH
OFFICE OF TECHNOLOGY TRANSFER
6011 EXECUTIVE BOULEVARD SUITE 325
BOX 13
ROCKVILLE MD 20852

SISSON, B

ART UNIT

PAPER NUMBER

1634

2

DATE MAILED:

08/28/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/084,691

Applicant(s)

Jens Bukh et al.

Examiner

Bradley L. Sisson

Group Art Unit

1634



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 and 32-58 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-20 and 32-58 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 3, drawn to DNA, classified in class 536, subclass 23.1.
- II. Claims 2 and 4-5, drawn to protein and claims 32 and 38, drawn to HCV genotype-specific peptides, all classified in class 530, subclass 350; claims 6-8, drawn to a recombinant method of synthesizing said proteins and recombinant method of making same; claims 9, 17, 47, and 48, drawn to expression vector, classified in class 435, subclass 320.1; and claim 10, drawn to host cell, classified in class 435, subclass 252.3.
- III. Claims 11-14, 33-36, 39-42, and 59, drawn to a method of detecting anti-HCV antibodies, and claims 15 and 37, drawn to a related kit, all classified in class 435, subclass 5.
- IV. Claims 18, 45, and 49, drawn to method of preventing hepatitis C infection, and claims 16, 19, 20, 43, 44, 46, 50, 51, drawn to a vaccine, all classified in class 514, subclass 2.
- V. Claims 52-54, drawn to antibodies, classified in class 530, subclass 388.3.
- VI. Claims 55-58, drawn to an immuno-based method of detecting corre proteins specific for a single genotype of HCV, classified in class 436, subclass 501.

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1. The inventions are distinct, each from the other because of the following reasons: ~~Inventions~~ I, II, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are all compounds *i.e.*, DNA, HCV proteins, and antibodies. Each of said compounds has different proerties and different effects.

2. Inventions II, III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are each drawn to different methods which are comprised of different method steps and result in different end-products.

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (DNA) as claimed can be used in a materially different process such as a hybridization rection.

4. Inventions II, III, IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

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claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (HCV proteins) can be used in any of the methods set forth in Groups III, IV, and VI.

5. Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed (antibodies) can be used in a materially different process such as an agent for passive immunization.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. A telephone call was made to Richard W. Bork, Reg. No. 36,459, on 25 August 1998 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978 and whose e-mail address is bradley.sisson@uspto.gov. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The fax phone numbers for Group 1630 are (703) 305-3014 and (703) 305-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

B. L. Sisson
BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP 1800 1630
8-26-98